

Xpert™
MRSA/SA SSTI

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Changing the paradigm for patient management.



In Vitro Diagnostic Medical Device

defining *on-demand* molecular diagnostics

 **Cepheid®**
Bring answers to life.

Xpert™ MRSA/SA SSTI: changing the paradigm for patient management.

The tremendous increase of both hospital acquired and community acquired MRSA in skin and soft tissue infections requires a change in management of these infections¹.

The Cepheid Xpert MRSA/SA SSTI test allows for the determination of the presence of *Staphylococcus aureus* or methicillin-resistant *S. aureus* in skin and soft tissue infections in less than one hour. Coupled with the simplicity of Cepheid's GeneXpert® System, results can now be available 24 hours a day, 365 days a year.

problem:

The most common etiologic agent of skin and soft tissue infections (SSTIs) is *S. aureus*. Staphylococci are the leading cause of superficial and deep pyogenic infections, bacteraemia, surgical wound infections, infections of bioprosthetic materials, and the second leading cause of nosocomial infections. Staphylococcal infections range in severity from trivial and self-limited to life-threatening². The morbidity and cost for cure associated with skin and soft tissue infections have been rising in recent years³ in parallel with the increasing prevalence of multidrug-resistant pathogens⁴⁻⁵.

solution:

As the therapy of choice significantly differs for *S. aureus*, MRSA, and Coagulase-negative Staphylococci (CONS), a rapid and reliable diagnostic test, confirming the presence of methicillin-susceptible vs. methicillin-resistant *S. aureus*, or excluding the presence of *S. aureus* would provide extremely valuable information for clinical decision-making⁶. Xpert MRSA/SA SSTI is a real-time test, performed within 50 minutes — sample to answer — anywhere in the hospital, 24 hours a day, 365 days a year. With the addition of Cepheid's Xpert MRSA/SA SSTI and blood culture tests, real-time *S. aureus* diagnostics have become a reality.

Xpert: in action

impact:

Xpert MRSA/SA SSTI provides results to physicians with unrivalled speed for timely and most appropriate preventive and therapeutic decisions. This means optimal patient management, targeted therapy where it matters, faster recovery, fewer therapeutic failures, and reduced likelihood of antibiotic resistance development. In a variety of settings, rapid detection of MRSA/SA will help the physicians to quickly diagnose and institute the proper therapy. **The test you have been waiting for!**



integrated:

The GeneXpert® System is the only system available that combines sample preparation with real-time PCR amplification and detection for fully-integrated and automated nucleic acid analysis. When running Xpert™ MRSA/SA SSTI, the system purifies, concentrates, detects and identifies targeted nucleic acid sequences for MRSA from blood cultures in less than one hour.

flexible:

Patients' SSTI's do not present positive in large numbers at the same time. The GeneXpert System reflects this model in its design and function. The system's unique random-access capability enables users to perform up to 16 different molecular tests concurrently. And because runs can be started at different times, multiple operators can easily use the GeneXpert System simultaneously. Now, inefficient batch processing is no longer your only rt-PCR option. With the GeneXpert System, blood cultures can be tested as they present, 24/7, 365 days a year.

Xpert: by design

easy to use:

The GeneXpert System provides state-of-the-art, real-time PCR results, but requires only minimal hands-on time. No additional equipment, special laboratory space, or special expertise is required. Users simply insert the biological sample for testing into a self-contained cartridge and the GeneXpert System does the rest.

Sensitive and Specific:

Appropriate patient management decisions can be made quickly.

Performance characteristics of Xpert™ MRSA/SA SSTI were determined in a multi-site prospective investigation study at three institutions by comparing the Xpert MRSA/SA SSTI assay on the GeneXpert® System with enriched culture, the most sensitive culture method.

Methicillin-resistant *Staphylococcus aureus*

		Culture		
		+	-	Totals
Xpert MRSA/SA	+	34	3	37
	-	1	76	77
		35	79	114

Sensitivity: 97.1%
Specificity: 96.2%

Staphylococcus aureus

		Culture		
		+	-	Totals
Xpert MRSA/SA	+	55	2	57
	-	0	57	57
		55	59	114

Sensitivity: 100%
Specificity: 96.6%

Comprehensive:

Confidence in your results.

	Type
Samples	Blood, Skin Lesion, Stool, Nasal, Abscess
SCCmec	II, IV, IVa, IVb, IVc

The analytical ubiquity (inclusivity) of the Xpert MRSA/SA assay was determined using 25 *Staphylococcus aureus* strains. These specimens are reported to be representative of MRSA and MSSA strains currently encountered in the health community. All MRSA strains were correctly reported MRSA positive and SA positive using the Xpert MRSA/SA assay. Additionally, each MSSA strain was correctly reported MRSA negative and SA positive.

Flexible:

Modular platform delivers the ideal system for your testing needs — upgrades are easy.

# of GX Sites	Tests completed		
	8 Hours	16 Hours	24 Hours
4	32	64	96
8	64	128	192
12	96	192	288
16	128	256	384

The Xpert™ MRSA/SA SSTI advantage: **simplicity**

- Fully automated process reduces handling time to just minutes
- Random access for flexibility and workflow optimization
- Rapid results to improve patient management
- Fully integrated reagent and instrument system for accuracy and reproducibility

1. Insert swab into Elution Reagent vial and break at score
2. Vortex and dispense Sample into port S
3. Dispense Reagent 1 into port 1
4. Dispense Reagent 2 into port 2
5. Insert cartridge and start assay

Total hands-on time = 2 minutes

Ordering Information

Xpert™ MRSA/SA SSTI Catalog No. GXMRSASA-SSTI-10
 (10 cartridges with reagents)

References:

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CORPORATE HEADQUARTERS

904 CARIBBEAN DRIVE
 SUNNYVALE, CA 94089
 USA
 TOLL FREE: 1.888.336.2743
 PHONE: 1.408.541.4191
 FAX: 1.408.734.1346

EUROPEAN HEADQUARTERS

VIRA SOLELH
 81470 MAURENS-SCOPONT
 FRANCE
 PHONE: 33.563.82.53.00
 FAX: 33.563.82.53.01

WWW.CEPHEID.COM



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